

REMARKS

Applicants have carefully reviewed and considered the Office Action mailed on December 1, 2004 and the documents cited therewith.

In view of the Requirement for Restriction, the Examiner has withdrawn claims 2-13, 15-26, and 28 from consideration. Applicant believes the Examiner intended the withdrawn claims to be 2-13, 16-26, and 28, based on the Form PTOL-326 and on his statement that claims 1, 14, 15, and 27 were examined on the merits. Clarification is requested.

Claims 1-28 are pending. No claim has been amended or cancelled.

Examiner Interview Summary

Applicant acknowledges the interview held on September 2, 2004 between Examiner Audet and Attorney Robin Chadwick, in which it was agreed that the Examiner would search Groups I and II (claims 1-28) as drawn to the elected invention (SEQ ID NOS: 8-10).

Information Disclosure Statement

Applicant submitted an Information Disclosure Statement and a 1449 Form on January 28, 2003. Applicant respectfully requests that initialed copies of the 1449 Forms be returned to Applicants' Representatives to indicate that the cited references have been considered by the Examiner.

§101 Rejection of the Claims

Claims 1, 14, 15, and 27 were rejected under 35 USC § 101 because the claimed invention is directed to non-statutory subject matter. The Examiner has suggested wording to show the "hand of man" in the claims, for example, by insertion of the word *isolated*. Office Action at page 2. This rejection is respectfully traversed.

The fact that the claimed peptides have been sequenced is evidence that the peptides have been taken out of their natural environment and purified to a degree sufficient to permit sequencing. Therefore, no additional wording is necessary.

The Examiner's reference to "[a]ll other claims" at the bottom of page 2 of the Office Action is not understood. The Examiner has indicated at the top of page 2 that claims 1, 14, 15, and 27 are the only claims that were examined on the merits. Accordingly, reference to and

rejection of “other claims” under 35 U.S.C. § 112, second paragraph appears inappropriate.

Clarification is requested.

Withdrawal of this rejection is respectfully requested.

§102 Rejections of the Claims

Claims 1, 14, 15, and 27 were rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent 6,399,371 to Falduto et al. The Examiner asserts that Falduto et al. discloses a 707 residue peptide (identified therein as SEQ ID NO: 20) allegedly encompassing Applicant's SEQ ID NO: 8 and products using this 707 residue peptide, allegedly disclosed at col. 8, lines 28-32.

Claims 1, 14, 15, and 27 were rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent Application Publication 2003/0199440 A1 to Dack et al. The Examiner asserts that Dack et al. discloses a 469 residue peptide (identified therein as SEQ ID NO: 23) and a 467 residue peptide (identified therein as SEQ ID NO: 31), allegedly encompassing Applicant's SEQ ID NOS: 9 and 10, respectively, and products using those peptides, in the abstract of Dack et al.

These rejections are respectively traversed.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ 2d 1913, 1920 (Fed. Cir. 1989). To constitute anticipation, the claimed subject matter must be identically disclosed in the prior art. *In re Arkley*, 172 U.S.P.Q. 524 at 526 (C.C.P.A. 1972). For anticipation, there must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the art. *Scripps Clinic & Res. Found. v. Genentech, Inc.*, 927 F.2d 1565, 18 USPQ2d 101 (Fed. Cir. 1991). To overcome the defense of anticipation, "it is only necessary for the patentee to show some tangible difference between the invention and the prior art." *Del Mar Engineering Lab v. Physio-Tronics, Inc.*, 642 F.2d 1167, 1172, (9th Cir. 1981).

Moreover, an anticipation rejection that is based on inherency must be supported by factual and technical grounds establishing that the inherent feature must flow as a necessary conclusion, not simply a possible conclusion, from the teaching of the cited art. *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Int. 1990); *In re Oelrich*, 666 F.2d 578, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981).

Contrary to the allegation of the Examiner, Falduto et al. does not teach products using the 707 residue peptide having SEQ ID NO: 20, nor is there a disclosure of the 707 residue peptide in combination with a pharmaceutically acceptable carrier. Falduto et al. is directed to a matrix metalloproteinase (MMP) named MMP-ABT and uses thereof. SEQ ID NO: 20 is disclosed at column 4, line 67 to column 5, line 1. SEQ ID NO: 20 is included in a list of known human MMPs, and is not part of the invention of Falduto et al.

Moreover, a mere disclosure of a 707 residue peptide does not disclose every element of Applicant's claims, whether or not the 707 residue peptide includes Applicant's SEQ ID NO: 8. Applicant has found that the linking regions spanning the two globular domains of matrix metalloproteinases act as inhibitors of matrix metalloproteinases. Specifically, a peptide comprising SEQ ID NO:8 can inhibit matrix metalloproteinase-2. Thus, for example, the presence of the phrase *wherein the peptide can inhibit matrix metalloproteinase-2*, means that the claimed peptide of claim 1 must be shorter than the 707 residue peptide of Falduto et al., because a matrix metalloproteinase cannot inhibit itself. As Applicant discloses at page 2 of the specification, chronic wounds do not heal because MMPs destroy the newly formed wound bed. MMPs are normally prevented from destroying the wound bed by the action of four tissue inhibitors of metalloproteinase (i.e., not the metalloproteinase itself). Accordingly, the phrase *wherein the peptide can inhibit matrix metalloproteinase-2* is not a mere recitation of intended use, and it must be given patentable weight. Apparently, the Examiner has not done so. Withdrawal of this rejection is respectfully requested.

Similarly, a mere disclosure of a 467 or 469 residue peptide does not disclose every element of Applicant's claims, whether or not that 467 or 469 residue peptide includes Applicant's SEQ ID NO: 9 or SEQ ID NO: 10. Contrary to the Examiner's allegation, Dack et al. does not teach products using the 467 or 469 residue peptides, nor does Dack et al. disclose these peptides in combination with a pharmaceutically acceptable carrier. Dack et al. is limited to disclosure of the 467 or 469 residue polypeptides as metalloproteinase *targets* of inhibitory agents. The invention of Dack et al. is actually drawn to inhibitory agents of such MMP targets. See page 17, paragraph [0233] et seq. There is no recognition by Dack et al. that any MMP sequence is an inhibitor of an MMP. Hence, a mere listing of full-length MMP sequences is not a disclosure of a peptide inhibitor of MMP.

Applicant has found that the linking regions spanning the two globular domains of matrix metalloproteinases act as inhibitors of matrix metalloproteinases. Specifically, a peptide comprising SEQ ID NO:9 or SEQ ID NO: 10 can inhibit matrix metalloproteinase-2. Thus, for example, the presence of the phrase *wherein the peptide can inhibit matrix metalloproteinase-2*, means that the claimed peptide of claim 1 must be shorter than the 467 or 469 residue peptides of Dack et al., because a matrix metalloproteinase cannot inhibit itself. As Applicant discloses at page 2 of the specification, chronic wounds do not heal because MMPs destroy the newly formed wound bed. MMPs are normally prevented from destroying the wound bed by the action of four tissue inhibitors of metalloproteinase. Accordingly, the phrase is not a mere recitation of intended use, and it must be given patentable weight. Apparently, the Examiner has not done so. Withdrawal of this rejection is respectfully requested.

Double Patenting Rejections

Claims 1, 14, 15, and 27 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-73 (i.e., claims 1 and 63) of copending Application No. 10/219,561 (Quirk et al., 2003/0166567) and claims 1-40 (i.e., claims 18 and 23) of copending Application No. 10/219,329 (Quirk et al., 2003/0096757 A1). Applicant respectfully requests that the Examiner hold these rejections in abeyance until there is an indication of allowable subject matter in the cited Applications.

However, the Examiner is respectfully requested to clarify which claims of the published Applications have been applied in these rejections. Specifically, it is unclear whether all the claims are applied or only those in the parenthetical phrases that follow the claim numbers.

Conclusion

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 373-6939 to facilitate prosecution of this application.


If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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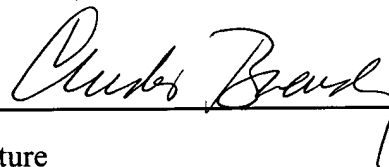
Date March 1, 2005

By _____
Robin A Chadwick
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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: MS Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 1st day of March, 2005.

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